

MAY 27 2004

K033663

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510(K) Summary

Submitted By: Lisa Peterson
Regulatory Affairs Specialist
Spinal Concepts, Inc.
5301 Riata Park Court, Bldg. F
Austin, TX 78727
512-918-2700

Date: November 20, 2003

Trade Name: Spinal Concepts Inc. Coda®
Classification Name: Vertebral Body Replacement
Product Code: MQP

Predicate Devices: Coda® is substantially equivalent to the SIGNUS TETRIS™ Spinal Implant, which was cleared for use as a vertebral body replacement device via K022793 (titanium version) and K031757 (PEEK version).

Device Description: Coda is manufactured from implantable grade titanium 6AL-4V alloy that conforms to ASTM F-136. The device consists of two opposing surfaces that make contact with the bony endplates of the vertebral bodies, and can be adjusted to provide from 0-11 degrees of lordosis.

Coda is available in two lengths and widths, and in various heights to provide the surgeon anatomic flexibility.

Intended Use: Coda is a vertebral body replacement device that is intended for use in the thoracic and/or thoracolumbar spine (T3 - L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture).

Coda is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. Coda is intended to be used with bone graft and supplemental fixation. Additionally, Coda is intended to be implanted in a paired configuration.

Substantial Equivalence: Mechanical testing demonstrated that Coda® exhibits the functional requirements to support its use as vertebral body replacement under normal physiologic loads in the spine.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 27 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Peterson
Regulatory Affairs Specialist
Spinal Concepts Incorporated
5301 Riata Park Court, Bldg. F
Austin, Texas 78727

Re: K033663
Trade Name: CODA® Vertebral Body Replacement Device
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: March 12, 2004
Received: March 15, 2004

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

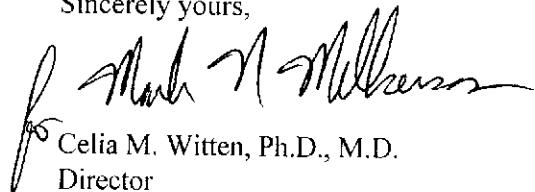
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Lisa Peterson

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a horizontal line.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Page 1 of 1

510(k) Number (if known): K 0 3 3 6 6 3

Device Name:

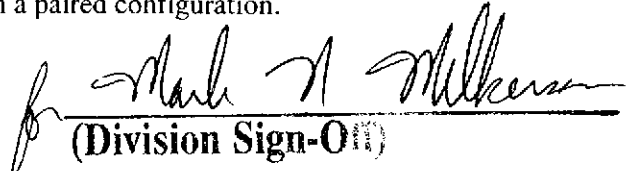
Spinal Concepts, Inc. Coda®

Indications for Use:

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K033663

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ☒ (Per 21 CFR 801.109)

OR

Over-The-Counter: ☐
(Optional Format 1-2-96)